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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/890,801 | 10/30/2001 | Stephen Edward Rees | 0459-0683P | 7859 |
| 2292 | 7590 | 05/05/2004 | EXAMINER | |
| BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747 | | | NASSER, ROBERT L | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3736 | 9 |

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/890,801

Applicant(s)

REES ET AL.

Examiner

Robert L. Nasser

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-6, 8-21, 23-29 and 49-56 is/are allowed.
- 6) ☒ Claim(s) 30, 33, 34, 37-39, 41, 43-48 and 57-59 is/are rejected.
- 7) ☒ Claim(s) 7, 22, 31, 32, 35, 36, 40 and 42 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

Claims 7, 22, 30, and 45-47 are objected to because of the following informalities: In claim 7, line 2, claim 22, line 2, and claim 30, line 30, applicant use the word asses instead of assess. Claims 45-47 are objected to in that they use the phrase "by means of ." This causes confusion as to whether applicant is invoking 35 USC 112, sixth paragraph. Applicant should amend the claim to state using rather than by means of. Appropriate correction is required.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

7(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 30, 33, 34, 37-39, 41, 43, 44, 45-48, and 57-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaffer et al. Shaffer et al shows a system that has a gas blender that mixes gas from two sources, an oxygen saturation measuring device (first detection means) that measures oxygen saturation and, if it deviates from a target level, adjust the fraction of inspired oxygen, which is measured with the processor (second detection means), to increase the oxygen saturation. In addition, In column 23, lines 13-20, Shaffer discloses that the device calculates the FiO_2 (fraction of oxygen in the mixture) necessary to achieve a target oxygen saturation. Claims 37-39 are rejected in that two respiratory parameters are determined based on two measurements (one each). With respect to claims 45-48, the device is useable on a person with COPD or to screen for COPD.

Claims 1-6, 8-21, 23-29 and 49-56 are allowable.

Claims 7, and 22 are objected too, as discussed above, but would be allowable if the spelling of assess were corrected.

Claims 1-14 and 49-56 define over the art in that none of the art determines respiratory parameters, as defined in the specification, based on two concurrent measurements of inspiratory or expiratory oxygen levels and blood oxygen levels, as claimed. Claims 15-29 define over the art in that none of the art has the computer adapted to determine if more measurements are required. In both sets of claims (10-14 and 15-29), the claims recite that the computer is adapted to make certain calculations. The examiner is interpreting the term "adapted" to mean programmed to make the calculations, as opposed to being capable of making the calculations.

Claims 31, 32, 35, 36, 40, and 42 would be allowable if rewritten to include all of the limitations of the base claim and any intervening claims. Claims 35, and 36 define over the art if record in that none of the art shows the recited third and fourth detection means. Claims 40 defines over the art in that none of the art calculates the oxygen consumption, as claimed. Claims 31, and 32 define over the art in that none of the art shows the methods of assessing the change in oxygen levels. Claims 42 defines over the art in that none of the art teaches using a gas with an oxygen level in the range claimed.

Applicant's arguments filed 2/6/2004 have been fully considered but they are not persuasive.

With respect to claim 30, applicant has stated that the device of Shaffer determines the parameter changes instantaneously and therefore there is no

motivation to adopt a scheme to predict the oxygen level needed. Applicant's attention is directed to column 23, lines 13-20, where such a scheme is disclosed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

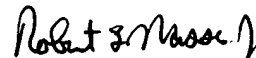
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (703) 308-3251. The examiner can normally be reached on Mon-Fri, variable hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert L. Nasser
Primary Examiner
Art Unit 3736



RLN
April 30, 2004

ROBERT L. NASSER
PRIMARY EXAMINER